

Atty Dkt. No.: UCAL-234  
USSN: 09/884,875

### REMARKS

#### FORMAL MATTERS:

Claims 1-10, 19-26, 28-31 and 43-48 are pending after entry of the amendments set forth herein.

Claim 27 has been canceled without prejudice.

Claim 7 has been amended to address a typographical error and claim 25 have been amended to incorporate the limitation of claim 27.

No new matter has been added.

#### ALLOWED CLAIMS

Applicants express gratitude in Examiner's indication that claims 1-6, 19-24, and 43-48 are allowable.

#### WITHDRAWAL OF PREVIOUS REJECTIONS

Applicants express gratitude in Examiner's indication that previous rejections have been withdrawn.

#### OBJECTIONS TO THE CLAIMS

Claim 7 has been objected to for informalities. In particular, the Office Action indicates that the word "level" in line 7 lacks the article "the". In view of the amendment to the claim, this objection may be withdrawn.

#### REJECTIONS UNDER § 112, ¶ 2

Claim 28 has been rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. In particular, the Office Action indicates that the term "detectable label" of claim 28 lacks antecedent basis in claim 25. In view of the amendment to claim 25, this rejection may be withdrawn.

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### **REJECTIONS UNDER §102**

Claims 25-26 and 29-31 have been rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Ganchi et al., Mol. Biol. Cell 3:1339-1352 (1992). In view the remarks made herein and amendments to the claims, this rejection may be withdrawn.

As noted in the specification, "the present invention is based on the discovery of a complementary control mechanism in the nucleus, involving reversible acetylation of the RelA subunit of NF- $\kappa$ B" (Specification, page 9, paragraph 47). Accordingly, the claimed invention is directed to method for identifying an agent that modulates NF- $\kappa$ B activity in transcription of a gene in a eukaryotic cell **by detecting the level of deacetylated RelA**. The methods involve administering a candidate agent and, for example, comparing the level of deacetylated RelA in the presence of the candidate agent to the level of deacetylated RelA in the absence of the candidate agent.

In contrast, Ganchi discloses a method for identifying an agent that modulates NF- $\kappa$ B activity by measuring the relative concentration in the cytoplasm and nucleus of Rel A (NF- $\kappa$ B p50). Nowhere does Ganchi disclose that the level of deacetylated RelA may be examined in order to screen candidate agents for activity in modulating NF- $\kappa$ B transcriptional activity, wherein the RelA is detectably labeled.

However, in the spirit of expediting prosecution and without conceding as to the correctness of this rejection, Claim 25 has been amended for clarification to recite "wherein the eukaryotic cell comprises a recombinant nucleic acid comprising a nucleotide sequence encoding RelA **operably linked to a detectable label**".

It is well established that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987), cert. denied, 481 U.S. 1052 (1987). See also, Scripps Clinic and Research Foundation v. Genentech, Inc., 18 USPQ 2d 1001 (Fed. Cir. 1991).

Ganchi fails to disclose the detection of a level of deacetylated RelA in response to exposure to a candidate agent. Moreover, Ganchi also does not disclose the use of a **detectably labeled RelA** in order

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to detect the level of deacetylated RelA. Therefore, Ganchi fails to anticipate the claimed invention because the cited reference does not teach each and every element as set forth in the claims.

In view of the above, the Applicant respectfully request that the rejection of Claims 25-26 and 29-31 under 35 U.S.C. §102(b) be withdrawn.

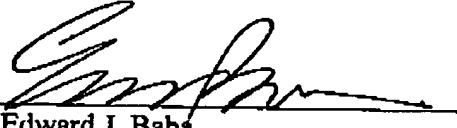
### CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL-234.

Respectfully submitted,  
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Date: July 13, 2005

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